

Amendment Under 37 C.F.R. 1.111  
Application No. 10/516,818  
Attorney Docket No. 043070

**REMARKS**

Claims 8-16 are currently pending.

**I. The IDS**

The Examiner has crossed off WO01/36012A1 on the PTO Form 1449. The Examiner states that a copy was not provided.

Filed concurrently herewith is an IDS that includes a copy of WO01/36012A1. Also listed in the IDS is EP 1230938, which the English language equivalent of WO01/36012A1.

**II. The Rejection under 35 U.S.C. 112**

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

**Claim 9**

The Examiner states that the meaning of “gradient of calcium phosphate” is unclear. The Examiner questions how does “gradient” define calcium phosphate in a composite having no structure?

The Examiner also states that the term “type” is relative and subjective in the phrase “one or more types of biodegradable polymeric materials”.

The Examiner states that the phrase “a composite thereof” is confusing since the claim contains no other material. The Examiner questions how a composite differs from the composite material of line 1 of claim 9.

**Claims 11, 12 and 13**

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The Examiner notes that claim 11 does not state any additional material besides the composite of claim 9. The Examiner states that it is unclear how “a scaffold” differs from the composite of claim 9.

The Examiner states that claim 12 merely sets forth an intended function of the scaffold of claim 11.

The Examiner states that claim 13, drawn to an “implant”, does not state any additional material besides the composite of claim 9 and similarly concludes that claim 13 is indefinite.

### **Claim 9**

Claim 9 has been amended to delete the term “type.”

The term “a composite thereof” is related to the biodegradable polymeric materials, not the “composite material” as indicated by the Examiner. For clarity, the term thereof is replaced and the components identified directly.

The term “composition gradient” has been deleted. As for the term “gradient” alone, Applicants respectfully submit that one skilled in the art would understand the meaning of gradient and that it may be any type of gradient. That is, the use of the broad term “gradient” should not be considered indefinite. See, for example Sherwood et al, cited by the Examiner, where gradients relevant to materials, macro architecture, microarchitecture, and mechanical properties are known.

Applicants also discuss embodiments of the term gradient in the specification. Applicants also respectfully submit that the present specification provides a fully enabling

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disclosure for the invention, as claimed, and that the disclosure would enable one of ordinary skill in the art to make and use the invention, as claimed, without undue experimentation.

Claim 9 has also been amended to more positively recite the relationship between the biodegradable polymeric material and the calcium phosphate.

### **Claims 11, 12 and 13**

For clarity, claims 11 and 13 have been amended to add additional component(s). New claim 15 also further recites that the scaffold is porous. Applicants respectfully submit that a scaffold and an implant are distinguishable from a composite material of the present invention.

For the above reasons, it is respectfully submitted that Applicants' claims are clear and definite and it is requested that the rejection under 35 U.S.C. §112 be reconsidered and withdrawn.

### **III. The Rejection under 35 U.S.C. 103(a)**

Claims 9-14 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Mattern et al. (6,969,523) or Yannas et al. (4,947,840) in view of Sherwood et al. (6,454,811).

Applicants respectfully submit that the present invention is not anticipated by or obvious over the disclosures of Mattern et al or Yannas et al in view of Sherwood et al and request that the Examiner reconsider and withdraw these rejections in view of the following remarks.

Mattern et al. and Yannas et al. do not describe anything concerning a gradient of calcium phosphate in a biodegradable polymeric material as well as not describing a method for achieving such a gradient.

Sherwood et al. also does not describe anything about a method for achieving a gradient

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of calcium phosphate in a biodegradable polymeric material such as glycosaminoglycan, collagen, and a composite of glycosaminoglycan and collagen.

The method described in Sherwood et al. cannot be applied to said composite as claimed. The method described in Sherwood et al, the “3DP process”, achieves a gradient of calcium phosphate in a device using a dispenser (dispensing module, see Fig. 1). In this method, the polymer component of the device is dissolved in an organic solvent such as chloroform, acetone, and ethanol (see Sherwood et al, column 9 line 40). However, biodegradable polymeric material such as glycosaminoglycan and collagen cannot solve in an organic solvent. Therefore, the method described in Sherwood et al. cannot be applied to the biodegradable polymeric materials such as glycosaminoglycan and collagen.

The gradient of calcium phosphate in a biodegradable polymeric material such as glycosaminoglycan, collagen, and a composite of glycosaminoglycan and collagen was achieved by the present invention for the first time; i.e. by alternately soaking one side or part of the biodegradable polymeric material in a calcium ion-containing solution and the other side or part in a phosphate ion-containing solution.

As such, a person skilled in the art could not have made the present invention, even if he would applied the 3DP method described in Sherwood et al. to the cross-linked collagen and glycosaminoglycan described in Mattern et al. and Yannas et al. That is, as discussed above, the 3DP method described in Sherwood et al. would simply not work with the biodegradable polymeric material such as glycosaminoglycan and collagen as claimed.

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For the above reasons, it is respectfully submitted that the subject matter of claims 9-15 is neither taught by nor made obvious from the disclosures of Mattern et al or Yannas et al in view of Sherwood et al and it is requested that the rejections under 35 U.S.C. §103(a) be reconsidered and withdrawn.

**IV. Conclusion**

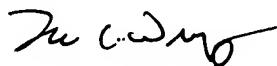
In view of the above, Applicants respectfully submit that their claimed invention is allowable and ask that the rejection under 35 U.S.C. §112 and the rejections under 35 U.S.C. §103 be reconsidered and withdrawn. Applicants respectfully submit that this case is in condition for allowance and allowance is respectfully solicited.

If any points remain at issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local exchange number listed below.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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